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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,372	07/02/2001	Mark E. Van Dyke	KER020/4-005CON	3035

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EXAMINER

GHALI, ISIS A D

ART UNIT PAPER NUMBER


1615

DATE MAILED: 01/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/899,372	Applicant(s) Van Dyke et al.
Examiner Isis Ghali	Art Unit 1615



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on Feb 28, 2002
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 55-96 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 55-96 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) Other:

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DETAILED ACTION

The receipt is acknowledged of applicants' change of address, filed 06/14/2002; request for extension of time,, both filed 10/25/2002; and the response to the office action mailed 5/14/2002 and the Terminal Disclaimer, both filed 10/31/2002.

Terminal Disclaimer

1. The terminal disclaimer filed on 10/31/2002 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patent 6,270,791 has been reviewed and is accepted. The terminal disclaimer has been recorded.

2. *The Standing Rejections:*

Claim Rejections - 35 USC § 103

Claims 55-96 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of US 4,495,173 ('173), US 5,276,138 ('138), US 5,763,583 ('583) or US 5,932,552 ('552) each by itself or in combination with any of US 5,948,432 ('432), US 5,900,245 ('245), US 5,358,935 ('935), or FR 2540381 ('381).

US '173 teaches composition comprising keratin and method for its production. Keratin is an inherent peptide. The process included the steps of oxidizing animal or

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human hair, feathers, claws, horns, hoofs, scales and the like. Oxidizing agents included peroxides or peracetic acid. The oxidation is followed by neutralization then gel filtration. Solvent used to solubilize keratin is ethanol or methanol. See col.2, lines 13-15, 21-24, 31-42; col.4, lines 52-55; col.5, lines 1-3, 53-54.

US '138 teaches a solubilized keratin, which is inherently a solubilized peptide, from animal hair or wool (abstract; col.65-67). The method of production included the steps of oxidation by hydrogen peroxide or peracetic acid; precipitation of a powder; and using solvent such as acetone, methanol or ethanol (col.3, lines 3-5, 21-24; col.4, lines 3, 20-28).

US '583 teaches a water soluble protein derived from human or animal hair (abstract; col.2, lines 15-18, 57-62; col.4, lines 49-50). The soluble protein is useful in cosmetics and medicines (col.6, lines 20-24). Protein is inherently a peptide. The soluble protein is produced by the process that comprised the steps of oxidation using hydrogen peroxide, neutralization of the produced aqueous solution followed by filtration (col.3, lines 20-25; col.4, lines 1-3, 14-23). Organic solvents are used such as methanol and ethanol (col.5, lines 66-67; col.6, lines 15-17). The produced soluble protein is in the form of film (col.5, line 45).

US '552 teaches a keratin hydrogel for wound dressing and scaffolding (abstract; col.2, lines 45-51; col.3, lines 19-25; col.5, lines 1-7). The hydrogel formed of soluble protein (protein is inherently a peptide). Derived from human or animal hair (col.2, lines

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52-54). The hydrogel is formed by a process comprising the steps of oxidation using peracetic acid, filtration, drying, forming a powder (col.2, lines 57-64; col.3, lines 40-65). The process also included the step of neutralization by a base (col.2, lines 67-col.3, line 3).

The references, however, do not teach the keratin sheet for medical application, the use of the recipient' hair , or the wound dressing comprising peptide.

US '432 discloses an insoluble keratin sheets for wound dressing and scaffolding where you can add another additives that help healing (abstract; col.5, lines 19-24).

US '935 teaches that the hair for production of the protein is obtained from the recipient (abstract).

U&S 245 teaches a tissue sealant comprising peptides (see col.9, lines 53, 59; col.12, line 45; col.14, lines 8-10).

FR '381 teaches peptides derived from keratin used to stimulate the cell growth (abstract).

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a wound dressing comprising peptide derived from the recipient' s hair and delivered on an insoluble keratin sheet. Motivation would arise from the knowledge in the dressing art or from the teaching of US '935 that the keratin derived from the recipient is non-antigenic; and from the teaching of FR '381 that the peptide stimulate the cell growth, and from the teaching of US '432 that the insoluble

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keratin sheet provides a non-antigenic sheet that can be shaped as needed before application to the wound and can be rehydrated to supple skin-like material (col.3, lines 12-24).

Response to Arguments

3. Applicant's arguments filed 10/31/2002 have been fully considered but they are not persuasive.

The main gist of applicants' argument is that the references do not teach the step of adding water miscible organic solvent to the water soluble peptide, such that a precipitate is formed.

In response to the above argument, the examiner position is that the claims are directed to product by a process, therefore, the claims are treated as product claims. The cited references teach the water soluble peptide or keratin. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., peptides are insoluble in alcohol) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicants claim only one property of the product, and that is water-soluble. Alcohol is

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only used in the step of precipitation of the water-soluble portion, and this portion can contain other ingredients other than peptides, as it is a middle step of the process. The claim language does not exclude other ingredients or other steps in the process. The burden is shifted to applicants to show the criticality of their product that contains water soluble and alcohol insoluble peptide, and the criticality of precipitating the peptide by alcohol over other precipitating agents disclosed by the references.

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5,047,249 disclosed a composition and method for treating skin conditions and promoting wound healing comprising keratin-derived protein.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Isis Ghali whose telephone number is (703) 305-4048. The examiner can normally be reached on Monday-Friday from 7:00 to 5:30 Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Isis Ghali

Patent Examiner

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
